UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	No. 20-CV-10488 (KMK) OPINION & ORDER

Appearances

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KENNETH M. KARAS, United States District Judge:

Regeneron Pharmaceuticals, Inc. ("Regeneron" or "Plaintiff") brings this Action seeking declaratory and injunctive relief against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of HHS ("Azar" or the "Secretary"), the Centers for Medicare & Medicaid Services ("CMS"), and Seema Verma, in her

official capacity as Administrator of CMS ("Verma" or the "Administrator"; collectively "Defendants"). Before the Court is an Order to Show Cause regarding Plaintiff's application for a preliminary injunction enjoining application of the Most Favored Nation Rule, 85 Fed. Reg. 76,180 ("MFN Rule"), to its drug EYLEA (aflibercept) Injection ("EYLEA"). (Order to Show Cause for Preliminary Injunction, Temporary Restraining Order, and Expedited Briefing Schedule ("OSC") (Dkt. No. 20).) For the reasons that follow, Plaintiff's application for a preliminary injunction is granted.

I. Background

On November 20, 2020, CMS released the Most Favored Nation ("MFN") Rule. Most Favored Nation Model, 85 Fed. Reg. 76,180 (Nov. 20, 2020) (to be codified at 42 C.F.R. pt. 513). "The MFN Model aims to take a global approach to calculating Medicare Part B drug payment amounts, by testing a new payment methodology that [1] takes into account the discounts that other countries enjoy [(the "MFN Price" component)]], and [2] pays providers and suppliers with a fixed add-on amount that does not reward the use of higher cost drugs [(the "alternative add-on payment" component)]." *Id*. at 76, 181. The MFN Rule was promulgated based on Section 1115A of the Social Security Act ("Section 1115A"), which allows CMS, through the Center for Medicare & Medicaid Innovation ("CMI") to "test payment and service delivery models." *Id*. at 76, 250; 42 U.S.C. § 1315a. This "test" will be in effect for seven years, with the MFN Price component phased in over the first three. 42 C.F.R. § 513.210(b)(8). Targeting some of Medicare Part B's top drug expenditures, the MFN Rule will apply to the top 50 drugs by aggregate allowed Medicare Part B charges (the "MFN Drugs"). *Id*. at § 513.130(a). Subject to certain exclusions, *id.* at § 513.130(b), participation is required for all providers and suppliers that submit a claim for an MFN Drug, *id*. at § 513.100(b). CMS did not follow notice

and comment procedures prior to promulgating the MFN Rule. *See* 5 U.S.C. § 553(b) & (c). Instead, it found that there was good cause to dispense with the notice and comment requirement of the Administrative Procedures Act ("APA"), supposedly due to the risks of high drug prices and the COVID-19 pandemic. 85 Fed. Reg. 76,248–76,249.

In announcing the MFN Rule, the President stated that it will "transform the way the U.S. government pays for drugs." Remarks by President Trump on Delivering Lower Prescription Drug Prices for All Americans (Nov. 20, 2020), https://www.whitehouse.gov/briefings-statements/remarks-president-trump-delivering-lower-prescription-drug-prices-americans/ ("MFN Announcement"). The President said that prior drug price reductions were "peanuts compared to what we've done with [most] favored nations," and that the MFN rule is "probably the biggest story that we've ever had relative to drug prices." *Id.* He further said "[n]obody has ever done this" and "there'll never be anything like this." *Id.* He indicated that "we're talking about savings of 50, 60, 70 percent, 80 percent." *Id.* Indeed, CMS estimates that the MFN Rule will save more than $85 billion for Medicare Part B, and $28.5 billion for beneficiaries. 85 Fed. Reg. 76,181.

In the same comments, the President indicated that the MFN Rule had been under consideration for at least two years. He stated that the MFN Rule "is something that has been talked about for many years, but nobody had the courage to do it." MFN Announcement. He also said that it "took a long time before we were able to do this because, statutorily, we had to go through a process." *Id.* He said the gap between U.S. and foreign prices has existed "for years," and "[w]e've been working on [the MFN Rule] for two years." *Id.* The Secretary echoed these comments, stating that he and the President "came up with the idea for Most Favored Nations status" at "the very first meeting we had in the Oval Office" after he became Secretary

in January 2018. *Id*. While the Secretary noted a recent application for approval of a vaccine, neither he nor the President discussed the role of the MFN Rule in responding to the COVID-19 pandemic. *Id*.

The regulatory record reflects this two-year history. On October 30, 2018, CMS issued an advance notice of proposed rulemaking (the "ANPRM"). Medicare Program; International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54,546 (Oct. 30, 2018). The ANPRM noted that U.S. drug acquisition costs exceed those of other developed countries, and that this leads to "unnecessary, potentially avoidable costs for Part B drugs." *Id*. at 54,550. It proposed an International Pricing Index model, which was to be tested in "selected geographic areas" pursuant to 42 U.S.C. § 1315a. *Id*. at 54,547. The ANPRM did not comply with the notice and comment requirements of 5 U.S.C. § 553(b) & (c). Instead, CMS promised that it "would implement [the model] through notice and comment rulemaking," *id*. at 54,550, and that "interested parties will also be provided an opportunity to comment on such information through subsequent proposed and final rulemaking documents," *id*. at 54,561.

On July 27, 2020, 21 months later, the President announced four executive orders focused on drug prices. *See Congress Didn't Act on Prescription Drug Prices. So President Trump Did*. (July 27, 2020), https://www.whitehouse.gov/articles/congress-didnt-act-on-prescription-drug-prices-so-president-trump-did/ ("Order Announcement"). The text of this Executive Order was released nearly two months later, on September 13, 2020. Exec. Order No. 13,948, Executive Order on Lowering Drug Prices by Putting America First (Sep. 13, 2020), https://www.whitehouse.gov/presidential-actions/executive-order-lowering-drug-prices-putting-america-first-2/ ("MFN Order"); *see also* Exec. Order No. 13,947, Lowering Drug Prices by Putting America First (July 24, 2020), https://www.govinfo.gov/content/pkg/DCPD-

202000674/html/DCPD-202000674.htm (noting the Sep. 13, 2020 release date for this Executive Order, which resembles and was superseded by the MFN Order). The MFN Order directed the Secretary to "immediately take appropriate steps to implement his rulemaking plan to test a payment model pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price." *Id*. It defined the "most-favored-nation price" as "the lowest price . . . for a pharmaceutical product that the drug manufacturer sells in a member country of the Organisation for Economic Co-operation and Development (OECD) that has a comparable per-capita gross domestic product." *Id*.

Plaintiff alleges, and Defendants do not refute, that EYLEA is among the 50 drugs covered by the MFN Rule, (Compl. ¶ 62 (Dkt. No. 1); Decl. of Richard O'Neal in Supp of Proposed OSC ("O'Neal Decl.") ¶ 16 (Dkt. Nos. 13)), and that the MFN Rule will reduce revenue from EYLEA and cause Plaintiff substantial financial harm, (O'Neal Decl. ¶¶ 21–33).

Plaintiff filed its Complaint on December 11, 2020. (Compl.). Since the MFN Rule will take effect on January 1, 2021, 42 C.F.R. § 513.1(c), Plaintiff immediately petitioned for emergency relief, including a preliminary injunction, (Proposed OSC (Dkt. No. 11); Decl. of Robert Allen in Supp. of OSC ("Allen Decl.") (Dkt. No. 12); O'Neal Decl.; Mem. of Law in Supp. of OSC ("Pl.'s Mem.") (Dkt. Nos. 14)).[1]

Also on December 11, 2020, the Court entered an Order to Show Cause, which established an expedited briefing schedule in light of the January 1 implementation date.

[1] Plaintiff also submitted a motion to seal portions of its memorandum and the O'Neal Declaration. (Not. of Pl.'s Mot. for Leave to File Under Seal (Dkt. No. 8); Decl. of Daniel Cellucci in Supp. of Pl.'s Mot for Leave to File Under Seal (Dkt. No. 9).)

(OSC.)[2] Defendants submitted their opposition on December 16, 2020. (Defs.' Opp. to Pl.'s Mot. for TRO and Prelim. Injunctive Relief ("Defs.' Mem.") (Dkt. No. 33).) Plaintiff submitted its reply on December 18, 2020. (Reply in Supp. of OSC (Dkt. No. 40); *see also* Dkt. No. 39 (unredacted version).) On the same date, Amicus Curiae American Society of Clinical Oncology ("Amicus") filed its brief. (Dkt. No. 37.) The Court held oral argument on December 22, 2020. (*See* Dkt. (minute entry for Dec. 22, 2020).) The following day, a court in the District of Maryland issued a temporary restraining order, which prevented the Government from implementing the MFN Rule for 14 days. (*See* Order (Dkt. No. 44, *Ass'n of Cmty. Cancer Ctrs. v. Azar*, 20-CV-3531 Dkt. (D. Md.)).) On December 28, 2020, a court in the Northern District of California issued an order (the "California Order") vacating the MFN Rule nationwide "pending completion of the notice and comment process." (*See* Order Granting Mot. for Prelim. Inj. (Dkt. No. 50, *Cal. Life Scis. Ass'n v. Cntr. for Medicare and Medicaid Servs.*, 20-CV-8603 Dkt. (N.D. Cal.)).)

II. Discussion

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008); *see also Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) ("[A] preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, by a clear showing, carries the burden of persuasion." (emphasis and quotation marks omitted)). "Preliminary injunctive relief is designed to preserve the status quo and prevent irreparable harm until the court has an opportunity to rule on the lawsuit's merits." *Williams v. Rosenblatt Sec., Inc.*, 136 F. Supp. 3d 593, 616 n.11

[2] The Court also granted Plaintiff's motion to seal portions of its submission, (Dkt. No. 23), and Plaintiff filed under seal unredacted copies of its memorandum and the O'Neal Declaration, (*see* Dkt. Nos. 26, 27).

(S.D.N.Y. 2015) (quotation marks omitted). "A party seeking a preliminary injunction must demonstrate: (1) a likelihood of success on the merits or sufficiently serious questions going to the merits to make them a fair ground for litigation and a balance of hardships tipping decidedly in the plaintiff's favor; (2) a likelihood of irreparable injury in the absence of an injunction; (3) that the balance of hardships tips in the plaintiff's favor; and (4) that the public interest would not be disserved by the issuance of an injunction." *Benihana, Inc. v. Benihana of Tokyo*, 784 F.3d 887, 895 (2d Cir. 2015) (alteration and quotation marks omitted). A preliminary injunction may be "warranted on the strength of the[] first two factors alone." *New York v. U.S. Dep't of Homeland Sec.*, 969 F.3d 42, 86 (2d Cir. 2020). The third and fourth factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009).

The Court finds that a preliminary injunction is appropriate. Plaintiff has demonstrated irreparable financial and reputational harm, a probability of success on its notice and comment claim, and that the balance of hardships and public interest favor an injunction.[3]

A. Irreparable Harm

A showing of irreparable harm is "the single most important prerequisite for the issuance of a preliminary injunction." *Faiveley Transp. Malmo AB v. Wabtec Corp.*, 559 F.3d 110, 118 (2d Cir. 2009). The "standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 22. Since it is "an extraordinary remedy," preliminary injunctive relief should not be issued "based only on a possibility of irreparable harm." *Id.* Further, irreparable harm "is neither remote nor speculative, but actual and imminent." *Faiveley Transp*, 559 F.3d at 118.

[3] Based on the emergency nature of Plaintiff's application, the Court will discuss only Plaintiff's claim regarding the notice and comment procedures required by the APA.

Plaintiff claims three types of irreparable harm, but the Court considers only two: (1) unrecoverable monetary harm; and (2) reputational harm. (Pl.'s Mem. 20–24.) The Court finds Plaintiff has shown irreparable harm.

1. Monetary Harm

"Monetary loss alone will generally not amount to irreparable harm . . . unless the movant provides evidence of damage that cannot be rectified by financial compensation." *Borey v. Nat'l Union Fire Ins. Co.*, 934 F.2d 30, 34 (2d Cir. 1991). However, where a plaintiff cannot recover damages due to sovereign immunity, monetary loss may amount to irreparable harm. *See United States v. New York*, 708 F.2d 92, 93 (2d Cir. 1983) (affirming the district court's finding that "[the plaintiff's] injury was irreparable even though [its] losses were only pecuniary because a suit in federal court against [the defendant,] New York[,] to recover the damages sustained by the plaintiff would be barred by the Eleventh Amendment"). Here, because the APA waives sovereign immunity only for "relief other than damages," 5 U.S.C. § 702, Plaintiff cannot recover its alleged financial losses.

Defendants cite some cases suggesting that the magnitude of the monetary harm affects whether it is irreparable. One such case held that an "alleged loss of $10 million per year . . . is not of sufficient magnitude in light of [the plaintiff's] annual revenues of $100 million." *ConverDyn v. Moniz*, 68 F. Supp. 3d 34, 48 (D.D.C. 2014). The Ninth Circuit requires a showing that the plaintiff "will lose considerable revenue." *California Pharmacists Ass'n v. Maxwell-Jolly*, 596 F.3d 1098, 1113–14 (9th Cir. 2010), *vacated and remanded sub nom. Douglas v. Indep. Living Ctr. of S. California, Inc.*, 565 U.S. 606 (2012). Further, the Court considers only "the harm arising during the interim between the request for an injunction and final disposition of the case on the merits." *Jayaraj v. Scappini*, 66 F.3d 36, 40 (2d Cir. 1995).

Plaintiff's uncontested declaration suggests that it will lose substantial revenue in 2021, based on the MFN Rule's methodology. (O'Neal Decl. ¶ 32.) Given the complexity of this case, it is unlikely that there will be final judgment before the end of next year, so Plaintiff's reliance on lost revenue for "the entirety of 2021" is appropriate. (*See* Defs.' Mem. 25.) While Plaintiff is a large corporation, the magnitude of its forecast revenue losses is unquestionably "considerable." Indeed, at least three circuits have held that unrecoverable damages may be irreparable harm, without reference to the amount of the loss. *See Odebrecht Const., Inc. v. Sec'y, Fla. Dep't of Transp.*, 715 F.3d 1268, 1289 (11th Cir. 2013) ("In the context of preliminary injunctions, numerous courts have held that the inability to recover monetary damages because of sovereign immunity renders the harm suffered irreparable."); *Chamber of Commerce v. Edmondson*, 594 F.3d 742, 770–71 (10th Cir. 2010) ("Imposition of monetary damages that cannot later be recovered for reasons such as sovereign immunity constitutes irreparable injury."); *Iowa Utilities Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996) ("The threat of unrecoverable economic loss . . . does qualify as irreparable harm."). Further, these financial losses result from both the MFN Price and alternative add-on payment components of the MFN Rule. (Oral Arg. 51–52.) Thus, the Court finds that Plaintiff will likely suffer irreparable financial loss absent a preliminary injunction.

2. Reputational Harm

A court can find irreparable harm based on "loss of reputation, good will, and business opportunities." *Register.com, Inc. v. Verio, Inc.*, 356 F.3d 393, 404 (2d Cir. 2004). This is because these damages "are difficult to establish and measure." *Id.*; *see also Ticor Title Ins. Co. v. Cohen*, 173 F.3d 63, 68–69 (2d Cir. 1999) (explaining that "it would be very difficult to calculate monetary damages that would successfully redress the loss of a relationship with a

client that would produce an indeterminate amount of business in years to come," and that this supports a finding of irreparable harm). Courts have determined that a loss of existing business and a decline in the opportunity for new business may qualify as irreparable harm. *See, e.g.*, *John E. Andrus Mem'l, Inc. v. Daines*, 600 F. Supp. 2d 563, 571–72 (S.D.N.Y. 2009) (finding irreparable harm due to harm to reputation where "physicians would cease" giving new business to the plaintiff and existing customers "would begin seeking alternative" arrangements); *Johnson Controls, Inc. v. A.P.T. Critical Sys., Inc*., 323 F. Supp. 2d 525, 532 (S.D.N.Y. 2004) (finding irreparable harm where complained of conduct would allow competitors to "lur[e] away the business of a number of [the plaintiff's] long-term . . . clients," and noting that "there is little guarantee that, should [the plaintiff] ultimately prevail in this action, these clients would return"); *see also Nalco Co. v. EPA*, 786 F. Supp. 2d 177, 188 (D.D.C. 2011) (finding irreparable harm where "customer would be unlikely to incur voluntarily such cost and disruption a second time to return to [the plaintiff's] product," as this would cause "the loss of long-standing clients that may be unwilling, or unable, to do business with [the plaintiff]" (alteration and quotation marks omitted)).

Plaintiff's uncontested declaration states that it will lose existing business and new customers to competitors as a result of the MFN Rule, and that these customers are unlikely to return. (O'Neal Decl. ¶¶ 21–28.) Plaintiff will lose this business in part because the EYLEA reimbursement rate will fall below doctors' acquisition costs, and doctors will use alternatives. (*Id.* at ¶¶ 23–27.) Even if Regeneron lowers the price of EYLEA, it will suffer reputational harm because it will need to renegotiate contracts, while its competitors will not. (*Id.* at ¶ 29.) The burden to renegotiate contracts is due to both the MFN Price and alternative add-on payment components of the MFN Rule. (Oral Arg. 19–20, 51.) This loss of business could be difficult to

measure in the same way as lost business in *Register.com* and *Ticor* was difficult to measure—particularly the loss of new customers. Defendants argue that "conclusory averments" of harmed reputation do not suffice. (Defs.' Mem. 26.) In the case Defendants cite, the plaintiff merely recited the standard for a preliminary injunction in a declaration, which was, unsurprisingly, insufficient to establish irreparable harm. *Rush v. Hillside Buffalo*, 314 F. Supp. 3d 477, 485 (W.D.N.Y. 2018) (finding overly conclusory a declaration stating "immediate and irreparable injury, loss, or damage will result to [the plaintiff] and that monetary damages at a later time will not adequately compensate him for injuries and damages he has sustained and is sustaining" (alterations omitted)). Here, the O'Neal Declaration cogently explains why the MFN Rule will cause reputational harm. (*See* O'Neal Decl. ¶¶ 21–28.) And the Court agrees that Mr. O'Neal is qualified to offer this assessment, based on his position and experience. (Pl.'s Reply 14–15; O'Neal Decl. ¶¶ 2–5.) Thus, the Court finds that Plaintiff will likely suffer irreparable reputational harm absent a preliminary injunction.[4]

[4] Defendants seek a stay of Plaintiff's application, arguing that the California Order undermines its claimed irreparable harm. (Dkt. No. 42.) The Court disagrees. Defendants may appeal the California Order. (*See id*. at 2 ("The Solicitor General has not determined whether to appeal or seek a stay pending appeal of the California Order.").) Indeed, appeal seems likely, as Defendants argued both here and in the Northern District of California that universal or nationwide injunctions are inappropriately broad, (*see* Defs.' Mem. 28–29; *see also* Defs.' Opp. to Pls.' Mot. for Prelim. Inj. at 20 (Dkt. No. 47, *Cal. Life Scis. Ass'n*, 20-CV-8603 Dkt. (N.D. Cal.))), and the Justice Department has taken the same position in other matters and in its internal litigation guidelines, (*see* Dkt. No. 44 at 2 (providing examples)). As a result, "the [Ninth] Circuit could alter the injunction at any moment," causing Plaintiff to "sustain irreparable harm immediately, before the Court could decide the merits of its claims." *California v. Health & Human Servs.*, 390 F. Supp. 3d 1061, 1066 (N.D. Cal. 2019). Further, "because this Court is governed by the law of a different circuit, the Court cannot conclude that a stay or decision on the merits from the Ninth Circuit . . . would resolve this case." *Nw. Immigrant Rights Project v. U.S. Citizenship & Immigration Servs.*, No. 19-CV-3283, 2020 WL 5995206, at *31 (D.D.C. Oct. 8, 2020). By contrast, where courts have stayed proceedings, it has been pending decisions that would establish controlling authority. *See Pars Equality Cntr. v. Trump*, No. 17-CV-255 (D.D.C. Mar. 2, 2018) (issuing a stay pending the Supreme Court's review of a parallel

B. Probability of Success

"To establish a likelihood of success on the merits, a plaintiff need not show that success is an absolute certainty. [It] need only make a showing that the probability of . . . prevailing is better than fifty percent." *Broker Genius, Inc. v. Volpone*, 313 F. Supp. 3d 484, 497 (S.D.N.Y. 2018) (quotation marks omitted) (citing *Eng v. Smith*, 849 F.2d 80, 82 (2d Cir. 1988)), *appeal dismissed as moot sub nom. Broker Genius Inc. v. Gainor*, 756 F. App'x 81 (2d Cir. 2019). The Court finds that Plaintiff has established a likelihood of success on its claim that Defendants failed to comply with the APA's notice and comment requirements. In the interest of releasing this Opinion & Order expeditiously, the Court does not evaluate and takes no position on Plaintiff's probability of success on its other claims. *See Forest City Daly Hous., Inc. v. Town of N. Hempstead*, 175 F.3d 144, 151 (2d Cir. 1999) ("[P]laintiff[] need[s] to show a likelihood of success with respect to only one of [its claims].").

1. Preclusion

Defendants argue that Plaintiff's claims are barred from judicial review, both under the Medicare Act generally, (Defs.' Mem. 7–9), and under Section 1115A, the statute authorizing CMS to test models, (*id*. at 9–13). The Court finds that Plaintiffs are likely to show that no statute bars its review of Plaintiff's notice and comment claim.

There is a "strong presumption that Congress intends judicial review of administrative action." *Smith v. Berryhill*, 139 S. Ct. 1765, 1776–77 (2019). "This presumption, however, may

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preliminary injunction that the Supreme Court stayed); *Hawai'i v. Trump*, 233 F. Supp. 3d 850 (D. Haw. 2017) (issuing a stay pending Ninth Circuit review of a parallel preliminary injunction). Finally, Defendants' proposed approach would leave "the resolution of important questions . . . to a single district court and to a single circuit, losing the benefit of the 'airing of competing views' on difficult issues of national importance." *Nw. Immigrant Rights Project*, 2020 WL 5995206, at *31 (quoting *Dep't of Homeland Sec. v. New York*, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring)).

be overcome by clear and convincing indications, drawn from specific language, specific legislative history, and inferences of intent drawn from the statutory scheme as a whole, that Congress intended to bar review." *Cuozzo Speed Techs. v. Lee*, 136 S. Ct. 2131, 2140 (2016) (quotation marks omitted).

a. Medicare Act

Defendants argue that judicial review of the MFN Rule is barred under the Medicare Act pursuant to 42 U.S.C. §§ 405(g), 405(h), and 1395ff. (Defs.' Mem. 7–9.)

The statutory framework referenced by Defendants consists of two components. The first establishes a procedure for obtaining judicial review of benefits decisions (the "Review Provisions"). 42 U.S.C. §§ 405(g), 1395ff. Section 405(g) of the Social Security Act provides that an individual "after any final decision" of the Secretary "made after a hearing to which he was a party . . . may obtain" judicial review. 42 U.S.C. § 405(g). This provision of the Social Security Act is incorporated into the Medicare Act by 42 U.S.C. § 1395ff(b)(1)(A), which states that "any individual dissatisfied with any initial determination under subsection (a)(1) shall be entitled to . . . judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title." This provision refers to subsection (a)(1), which provides authority for the Secretary to "promulgate regulations and make initial determinations with respect to benefits under part A or part B." *Id.* at (a)(1).

The second component (the "Preclusion Provision") bars judicial review when claimants do not comply with the Review Provisions. 42 U.S.C. § 405(h). Section 405(h) of the Social Security Act bars "action[s] against the United States . . . brought under section 1331 or 1346 of

Title 28 to recover on any claim arising under this subchapter."[5] 42 U.S.C. § 405(h). The statute also states that "[n]o findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided." *Id.* This Social Security Act provision is incorporated into the Medicare Act by 42 U.S.C. § 1395ii, which states that § 405(h) "shall . . . apply with respect to this subchapter." The referenced subchapter is Subchapter XVIII, which is the Medicare Act. *See Turecamo v. Comm'r*, 554 F.2d 564, 566 n.1 (2d Cir. 1977) (describing "Subchapter XVIII of the Social Security Act" as "[t]he Medicare statutory framework").

Plaintiff argues that both the Review Provisions and the Preclusion Provision are inapplicable. (Pl.'s Reply 2.) The Court agrees.

The Review Provisions are inapplicable for two reasons. First, the MFN Rule does not cite 42 U.S.C. § 1395ff as a source of authority. *See* 85 Fed. Reg. 76,250. As a result, Plaintiff's claims do not arise "under subsection (a)(1)" of § 1395ff, and Plaintiff is not bound by procedural requirements specific to such claims. *See* 42 U.S.C. § 1395ff(b)(1)(A). Neither of the sources of rulemaking authority cited in the MFN Rule similarly incorporates § 405(g). *See* 42 U.S.C. §§ 1302, 1395hh; *see also* 85 Fed. Reg. 76,250 (listing sources of authority for MFN Rule). Second, even if Plaintiff were subject to this requirement, it applies only to "any initial determination under subsection (a)(1)." *Id.* Subsection (a)(1) authorizes the Secretary to "promulgate regulations and make initial determinations with respect to benefits under part A or part B." *Id.* at (a)(1). Plaintiff challenges a regulation, not an initial determination, so this

[5] This sentence "reaches beyond ordinary administrative law principles of ripeness and exhaustion of administrative remedies . . . by preventing the application of exceptions to those doctrines." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 2 (2000). Thus, Plaintiff's briefing on the general exhaustion requirement, (*see* Pl.'s Reply 3), is not applicable to this sentence of the Preclusion Provision.

provision does not apply. (*See* Pl.'s Reply 2.) Indeed, a separate, also inapplicable provision limits judicial review of regulations. *Id.* at (e)(1) ("A regulation or instruction that relates to a method for determining the amount of payment under part B and that was initially issued before January 1, 1981, shall not be subject to judicial review.").

The Preclusion Provision is also inapplicable. The Court considers its two relevant sentences in turn. As discussed, the second sentence of § 405(h) bars review by "any . . . tribunal" of any "findings of fact or decision" of the Secretary, "except as herein provided." *Id.* The Supreme Court has held that an "attack on [a] regulation . . . is not subject to such a requirement because there is no hearing," and the first sentence of § 405(h) contextually defines "'decision' . . . as those determinations made by 'the Secretary after a hearing.'" *Bowen v. Michigan Acad. of Family Physicians*, 476 U.S. 667, 679 n.8 (1986); *see also* 42 U.S.C. § 405(h) ("The findings and decision of the Commissioner of Social Security after a hearing shall be binding . . . ."). Because the MFN Rule was not promulgated "after a hearing," *see generally* 85 Fed. Reg. 76,180, the second sentence does not apply.

The third sentence of § 405(h)—which is the focus of the briefing—does not bar review because it applies to Subchapter XVIII, and Plaintiff's claim arises under Subchapter XI. As discussed, the last sentence of § 405(h) bars federal courts' jurisdiction only for "any claim arising under this subchapter." 42 U.S.C. § 405(h). And § 1395ii applies this provision only "with respect to this subchapter." 42 U.S.C. § 1395ii. Section 1395ii also is located in Subchapter XVIII. By contrast, Section 1115A and the Secretary's source of rulemaking authority under Section 1115A are both located in Subchapter XI. *See* 42 U.S.C. §§ 1302, 1315a. Neither section incorporates § 405(h), *id.*, but other provisions of Subchapter XI do, *see,*

e.g., 42 U.S.C. § 1320a-7(f)(3), suggesting that Congress did not intend § 405(h) to apply to §§ 1302 or 1315a.

At oral argument, Defendants asserted that the Supreme Court has construed the "claim arising under" language broadly. (Oral Arg. 25, 32 (citing *Heckler v. Ringer*, 466 U.S. 602, 615 (1984) and *Sensory Neurostimulation, Inc. v. Azar*, 977 F.3d 969, 979 (9th Cir. 2020)).) But the Supreme Court has not rewritten the statute, and neither will this Court. Indeed, *Ringer* states that a claim arises under the Medicare Act when it provides "both the standing and the substantive basis for the presentation of the claim[]," even where the plaintiff alleges a violation of APA procedural law. *Ringer*, 466 U.S. at 615, 622. In other words, *Ringer* broadened § 405(h)'s preclusion of review to include APA claims, but not to include different subchapters. *Id.* Here, it is true that Plaintiff's notice and comment claim is not unrelated to the Medicare Act. For example, the challenged MFN Rule cites as authority one section within Subchapter XVIII, *see* 85 Fed. Reg. 76,250 (citing as authority 42 U.S.C. § 1395hh), and Plaintiff seeks to reinstitute the average sales price model required under Subchapter XVIII, (Oral Arg. 32). However, Plaintiff's standing is due to alleged harm from a regulation promulgated pursuant to § 1315a of Subchapter XI. (*See generally* Compl.) Similarly, Plaintiff's notice and comment claim is substantively based on Defendants' failure to follow the procedures required by the APA to promulgate a regulation under § 1302 of Subchapter XI. (*Id.*) Thus, *Ringer* does not apply. Nor does *Sensory Neurostimulation*, which simply extended the principle from *Ringer*—that § 405(h) can preclude review of APA claims—to lawsuits brought by a third party. 977 F.3d at 980.

Even where § 405(h) would otherwise bar review, the Supreme Court recognizes an exception: § 405(h) "does not apply . . . where application of § 405(h) would not simply channel

review through the agency, but would mean no review at all." *Ill. Council*, 529 U.S. at 19. While the Second Circuit has not addressed the exception in *Illinois Council* in depth, according to the Fifth Circuit, courts of appeal are fairly uniform in requiring a plaintiff to show "there is no way of having their claims reviewed, there is complete preclusion, or there exists a serious practical roadblock to having their claims reviewed in any capacity, administratively or judicially." *Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649, 655 (5th Cir. 2012) (quotation marks omitted). This standard is not met where "third-party physicians [are] sufficient proxies for [the plaintiffs] since the physicians had adequate financial incentive to pursue a regulatory challenge on [the plaintiffs'] behalf." *Sw. Pharmacy Sols., Inc. v. Centers for Medicare & Medicaid Servs.*, 718 F.3d 436, 445 (5th Cir. 2013). However, the standard is met where the possible proxies have "little incentive to pursue the [plaintiff's] challenge to the regulations." *Council for Urological Interests v. Sebelius*, 668 F.3d 704, 713 (D.C. Cir. 2011).

Here, Plaintiff is more likely than not eligible for the *Illinois Council* exception. There are two competitors to EYLEA that are not covered by the MFN Rule: off-label Avastin and recently approved Beovu. (O'Neal Decl. ¶¶ 24–25.) Under the MFN Rule, Plaintiff claims, and Defendants do not refute, that it faces one of two alternatives. First, doctors switch to one of these competitors. (*Id.* at ¶¶ 23–27.) Or, second, Plaintiff reduces the price of EYLEA. (*Id.* at ¶ 29.) Under neither scenario would prescribers have a financial incentive to challenge the MFN Rule on behalf of Plaintiff. Nor would patients, who would be paying a lower price. Further, unlike cases where the Fifth Circuit has found sufficient proxies, Plaintiff does not have a direct link to providers. *See Sw. Pharmacy Sols.*, 718 F.3d at 446 (finding plaintiff could challenge regulation through one of its enrollees); *Nat'l Athletic Trainers' Ass'n*, 455 F.3d at 507 (finding that physicians employing trainers to reduce costs could seek review on the trainers' behalf).

(*See also* Compl. ¶ 23 (noting that Plaintiff "first sell[s] the drugs to wholesalers, who then sell those drugs to pharmacies, hospitals, doctors, and other healthcare providers").) Amicus's brief suggests that providers of drugs for which there are no such substitutes may have an incentive to challenge the MFN Rule. (*See* Amicus Br. 4–7.) And at oral argument, Defendants explained that various provider groups have already filed suit. (Oral Arg. 53–54.) But Defendants also pointed out that any injunctive relief should be limited to Regeneron, (Defs.' Mem. 28–29), so it is not clear that these lawsuits, if successful, would result in Plaintiff's sought-after relief. Thus, the Court on this record finds it more likely than not that there are no adequate proxies to advance Plaintiff's individual claim, and that Plaintiff qualifies for the *Illinois Council* exception to § 405(h).

b. Section 1115A

Defendants argue that judicial review of the MFN Rule is barred under Section 1115A. (Defs.' Mem. 9–13.) Section 1115A bars "administrative or judicial review" of several facets of models selected for testing, including "the selection of models for testing or expansion," *id*. at (d)(2)(A), "the selection of organizations, sites, or participants to test those models selected," *id*. at (d)(2)(B), and "the elements, parameters, scope, and duration of such models for testing or dissemination," *id*. at (d)(2)(C). Since the statute's "intent to bar review is clear, . . . [the Court] determine[s] only whether the challenged action falls within the preclusive scope of the statute." *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 505–06 (D.C. Cir. 2019).

In arguing that Section 1115A bars Plaintiff's notice and comment claim, Defendants rely on case law interpreting § 405(h), and in particular on *Ringer*. (Defs.' Mem. 12–13.) But § 405(h) is a separate preclusion provision, in a separate subchapter, and there is no reason to read it into Section 1115A because Section 1115A is "in the Medicare context." (Defs.' Mem.

12.) Section 1115A merely bars judicial review of particular facets of CMI's models. *See* 42 U.S.C. § 1315a(d). It does not bar review of the propriety of the procedures used for establishing such models. *See generally id*. If Congress intended to bar review of rulemaking procedures, it could have precluded review of the "establishment" of these models. *See* 42 U.S.C. § 1395nn(i)(3)(I) ("There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise of the process under this paragraph (including the establishment of such process)."). Because it did not, and because Plaintiff is "seeking review of the promulgation of the Secretary's rules and policies, separate from the substance of any such rules or policies," Section 1115A does not overcome the "presumption of review." *Yale New Haven Hosp. v. Azar*, 409 F. Supp. 3d 3, 15 (D. Conn. 2019).

2. Notice and Comment

The Court finds that Plaintiff is more likely than not to prevail on its notice and comment claim. (*See* Compl. ¶¶ 71–80.)

The Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq.*, governs the procedural requirements for agency decision-making, including the rulemaking process. Prior to formulating, amending, or repealing a rule, agencies must engage in a notice-and-comment process. 5 U.S.C. §§ 551(5), 553. Notice must include "the legal authority under which the rule is proposed," and "either the terms or substance of the proposed rule or a description of the subjects and issues involved." *Id.* § 553(b). The public may then submit comments which the agency must consider before promulgating a final rule. *Id.* § 553(c). Specifically, "the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." *Id.* To satisfy the requirements of § 553, notice of a proposed rule must

"provide an accurate picture of the reasoning that has led the agency to the proposed rule," so as to allow an "opportunity for interested parties to participate in a meaningful way in the discussion and final formulation of rules." *Conn. Light & Power Co. v. Nuclear Regul. Comm'n*, 673 F.2d 525, 528–30 (D.C. Cir. 1982). The Medicare Act similarly requires that "before issuing in final form any regulation under subsection (a), the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon." 42 U.S.C. § 1395hh(b)(1). Both statutes contain an exception "when the agency for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B); *see also* 42 U.S.C. § 1395hh(b)(2)(C) (subsection (b)(1) does not apply where "subsection (b) of section 553 of Title 5 does not apply pursuant to subparagraph (B) of such subsection"). As discussed, the APA provision applies to regulations like the MFN Rule that are promulgated pursuant to 42 U.S.C. § 1302. *See* 5 U.S.C. § 553(a) (discussing applicability of § 553 procedure requirements).

Defendants do not argue that they provided adequate notice and opportunity to comment. Instead, they argue that they had good cause to find that notice and comment procedures would be "contrary to the public interest." (Defs.' Mem. 13–17.) Thus, the key question is whether Defendants made an adequate finding of good cause.

"The burden is on the agency to establish that notice and comment need not be provided." *Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 113–14 (2d Cir. 2018). "The good cause exception should be narrowly construed and only reluctantly countenanced." *Id.* at 114 (citation and quotation marks omitted). "It is generally limited to emergency situations, or where delay could result in serious harm." *Id.* (quotation marks

omitted). A court should only agree with a finding of good cause "in the rare circumstance when ordinary procedures—generally presumed to serve the public interest—would in fact harm that interest." *Id*. However, a finding of good cause is "an important safety valve to be used where delay would do real harm." *United States v. Dean*, 604 F.3d 1275, 1279 (11th Cir. 2010). The Court's review of the finding of good cause is "de novo," but the Court "defer[s] to an agency's factual findings and expert judgments." *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 706 & n.3 (D.C. Cir. 2014). The Court does not consider the justifications in isolation, but considers "the combined effect" of the reasons given by the Government. *Nat'l Women, Infants, & Children Grocers Ass'n v. Food & Nutrition Serv.*, 416 F. Supp. 2d 92, 107 (D.D.C. 2006).

Here, CMS found "good cause," for two reasons: the general risks of high drug prices and the collateral effects of the COVID-19 pandemic. 85 Fed. Reg. 76,248–76,249. Regarding the risk of high drug prices, CMS stated that "[h]igh drug prices in the U.S. have serious economic and health consequences for beneficiaries in need of treatment." *Id*. at 76,249. High drug prices cause beneficiaries "to divert scarce resources to pharmaceutical treatments or skip doses." *Id*. Further, more than "two thirds" of the increase in Medicare Part B drug spending was due to an increase in price. *Id*. Regarding the COVID-19 pandemic, CMS stated that "[h]igh drug prices could cause improper medication adherence or skipped treatment," causing "poor clinical outcomes for chronic disease management." *Id*. Further, older adults with chronic illness are at the highest risk of severe illness from COVID-19. *Id*. In addition, the COVID-19 pandemic has increased unemployment and food prices. *Id*. As a result, seniors living on fixed income—including "the 6 million Medicare FFS beneficiaries without supplemental coverage and over 12 million beneficiaries dually eligible for Medicare and Medicaid"—require "urgent relief from high drug prices in order to prevent stinting on care and alleviate general financial

instability worsened by the COVID-19 pandemic." *Id*. Despite some positive economic and employment trends, a "new surge" of cases "may lead to additional hardship and requires immediate action." *Id*. Defendants rely particularly on CMS's identification of this "new surge" to justify its finding of good cause. (Defs.' Mem. 14–16.) Notably, the MFN Rule apparently is not intended to facilitate treatment of COVID-19, because drugs granted Emergency Use Authorization ("EUA") to treat COVID-19 are excluded from the rule.
42 C.F.R. § 513.130(b)(ix). At oral argument, Defendants argued that this is incidental, because the federal government pays for most COVID-19 treatments and vaccines. (Oral Arg. 40.)

The risks of high drug prices are unlikely to support a finding of good cause because CMS was aware of this problem for years and failed to act. In the ANPRM issued more than two years ago, CMS noted that higher cost drugs "are driving increasing Part B drug expenditures," 83 Fed. Reg. 54,549, and that "acquisition costs in the U.S. were 1.8 times higher than in comparator countries," *id*. at 54,550. Indeed, the MFN Rule itself refers to a 2018 analysis showing that "[d]rug acquisition costs in the U.S. exceed those in Europe, Canada, and Japan." 85 Fed. Reg. 76,183. That "some semblance of the [MFN] Rule has been on [CMS's] regulatory agenda" since 2018 suggests that the agency could have acted sooner and complied with the notice and comment requirements. *Chamber of Commerce v. DHS*, No. 20-CV-7331, 2020 WL 7043877, at *8 (N.D. Cal. Dec. 1, 2020). Put bluntly, an agency's self-imposed delay cannot support a finding of good cause. *See Nat. Res. Def. Council*, 894 F.3d at 114–15 ("Good cause cannot arise as a result of the agency's own delay, because otherwise, an agency unwilling to provide notice or an opportunity to comment could simply wait . . . raise up the 'good cause' banner and promulgate rules without following APA procedures."); *Nat. Res. Def. Council v. Abraham*, 355 F.3d 179, 205 (2d Cir. 2004) ("[A]n emergency of [CMS's] own making can[not]

constitute good cause."). Thus, CMS's finding regarding the risks of high drug prices does not suffice to show good cause.

The same is true of the COVID-19 pandemic, for three reasons. First, the MFN Rule's rationale—the health risks and economic risks to Medicare Part B beneficiaries during the pandemic—does not support a finding of good cause. Regarding health risks, CMS does not suggest that the MFN Rule will improve COVID-19 outcomes. It states that "high drug prices could lead to improper medication adherence or skipped treatment," and that this "can result in poor clinical outcomes for chronic disease management." 85 Fed. Reg. 76,249. CMS continues that "[t]he risk of severe illness from COVID-19 increases with age and the presence of chronic illness." *Id*. But it does not link these two statements. *Id*. It does not cite *any* studies or otherwise draw the conclusion that better chronic disease management improves COVID-19 outcomes. *See Ass'n of Cmty. Cancer Ctrs. v. Azar*, No. 20-CV-3531, 2020 WL 7640818, at *7 (D. Md. Dec. 23, 2020) ("[F]or the proposition, central to CMS's justification for dispensing with notice and comment, that 'the COVID-19 pandemic has rapidly exacerbated' the problem of high drug prices, CMS does not cite to any source at all."). There is little question that the COVID-19 pandemic is "a situation of acute health or safety risk." *Nat. Res. Def. Council*, 894 F.3d at 115. However, because the MFN Rule does not claim to improve outcomes from the virus, it cannot point to these risks as good cause. *See Ass'n of Cmty. Cancer Ctrs.*, 2020 WL 7640818, at *7 ("In its rationale, CMS cites fifteen distinct sources in support of its various assertions, but most of those sources link to studies relating to drug pricing and health indicators from well before the pandemic existed, and none specifically address the cost of the particular drugs covered by the rule."). Regarding the economic risks, there is a "mismatch of facts regarding the unemployment caused by the proliferation of the pandemic and the classes of

[individuals] impacted by the [MFN] Rule[]." *Chamber of Commerce*, 2020 WL 7043877, at *10 (citation and quotation marks omitted). CMS states that the vulnerable population includes "seniors, particularly those who live on fixed incomes, such as the 6 million Medicare fee-for-service beneficiaries without supplemental coverage and over 12 million beneficiaries dually eligible for Medicare and Medicaid." 85 Fed. Reg. 76,249. CMS also states that COVID-19 has caused high levels of unemployment. *Id*. However, it does not state that higher unemployment has affected the target population—which includes seniors and fixed income recipients (who may be less likely to rely on wages). *See Ass'n of Cmty. Cancer Ctrs.*, 2020 WL 7640818, at *7 ("[T]he agency does not indicate in its rationale the extent to which these beneficiaries will experience immediate economic relief as a result of reduced copays under the MFN rule . . . ."). CMS also states that COVID-19 has raised food prices. 85 Fed. Reg. 76,249. However, the cited article refers to food insecurity generally due to unemployment. Bridget Balch, *54 million people in America face food insecurity during the pandemic. It could have dire consequences for their health*, AAMC (Oct. 15, 2020), https://www.aamc.org/news-insights/54-million-people-america-face-food-insecurity-during-pandemic-it-could-have-dire-consequences-their. Thus, CMS provides no support for its conclusion that food prices are higher due to the COVID-19 pandemic. 85 Fed. Reg. 76,249; *see also Capital Area Immigrants' Rights Coal. v. Trump*, No. 19-CV-2117, 2020 WL 3542481, at *16 (D.D.C. June 30, 2020) (finding no good cause where an agency "rel[ied] on a single newspaper article that does not even directly address the key predictive judgment in question").

Second, the "new surge" does not justify the MFN Rule. The MFN Rule indicates that "we have seen some positive economic and employment trends since the initial peak in April." 85 Fed. Reg. 76,249. This information does not suggest a "dire emergency." *See Chamber of*

Commerce, 2020 WL 7043877, at *10 (quotation marks omitted). The Secretary finds that this "new surge in COVID-19 cases . . . may lead to additional hardship and requires immediate action," and cites a Center for Disease Control and Prevention ("CDC") study showing an expected increase in cases. 85 Fed. Reg. 76,249. Neither the MFN Rule nor the CDC study suggests that the "positive economic and employment trends" will be reversed, much less that these indicators will reach the level of "the initial peak in April." *See id.*; CDC, *COVID–19 Forecasts: Cases* (last visited Dec. 23, 2020), https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/forecasts-cases.html. CMS could have announced a NPRM in April, when these effects were at their worst. It could have done the same in July 2020, when the President announced his executive orders on drug prices, Order Announcement, and COVID cases increased in some parts of the country, *see* CDC, *Previous COVID-10 Forecasts: Cases* (last visited Dec. 23, 2020) (forecast from September 3, 2020), https://www.cdc.gov/coronavirus/2019-ncov/covid-data/forecasting-us-cases-previous.html. Delays after the MFN Order suggest a lack of urgency, including the two months between the executive order being announced and publicly issued, *see* Order Announcement; MFN Order, and the two months between the executive order being issued and the MFN Rule being promulgated, *see* MFN Order; 85 Fed. Reg. 76,180.

Third, the approach of the MFN Rule does not fit with the claimed good cause. The MFN Rule is designed to last seven years. 43 C.F.R. § 513.210(b)(8). It is not "intended to be a temporary solution until the emergency situation has been eased by [its] promulgation." *Chamber of Commerce*, 2020 WL 7043877, at *10 (quotation mark omitted). Indeed, because it is phased in, the biggest effects will be after 2021, when the COVID-19 pandemic will presumably be a less severe problem, thus thoroughly undercutting this as the basis for good

cause. *See Ass'n of Cmty. Cancer Ctrs.*, 2020 WL 7640818, at *8 ("Where, as here, the purpose of the rule is to test, over a period of seven years, a transformative new model of drug reimbursements that may affect untold numbers of beneficiaries and billions of dollars in spending on pharmaceuticals, there is a significant benefit in providing advance notice and comment procedures, and nothing in the agency's rationale explains why the relatively brief delay that would result from a notice and comment period would obstruct the purpose of testing such a long-term model."). And in announcing the MFN Rule, neither the President nor the Secretary nor the Administrator mentioned the MFN Rule's role in addressing the COVID-19 pandemic. MFN Announcement. Instead, the President described the MFN Rule as "transform[ing] the way the U.S. government pays for drugs" and "probably the biggest story that we've ever had relative to drug prices." *Id*. Consistent with this view of the MFN Rule as transformational, it is much more sweeping than the Medicare Part B population particularly affected by the COVID-19 pandemic. It covers *all* of Medicare Part B beneficiaries, not just the six million fee-for-service beneficiaries without supplemental coverage, and not just the 12 million beneficiaries dually eligible for Medicare and Medicaid. *See* 42 C.F.R. § 513.100(b); *Ass'n of Cmty. Cancer Ctrs.*, 2020 WL 7640818, at *7 ("[T]he agency . . . concedes . . . that the number of Medicare beneficiaries with supplemental coverage vastly outnumbers those without such supplemental coverage."). Nor is it focused on drugs treating chronic conditions that may worsen COVID-19 outcomes. *See* 42 C.F.R. § 513.100(b). Even accepting Defendants' argument that "the good cause does not have to be tied to the entirety of the rule," (Oral Arg. 40), this lack of fit undermines Defendants' good cause claims. It suggests that the claimed good cause weighs relatively lightly against the much heavier risk of failing to "foster reasoned decisionmaking" by "providing a forum for the robust debate of competing and frequently

complicated policy considerations having far-reaching implications." *Nat. Res. Def. Council*, 894 F.3d at 115. Notice and comment procedures are particularly important for regulations that will "transform the way the U.S. government pays for drugs," MFN Announcement, and about which there is significant debate, (*see* Amicus Br. 4–9; Oral Arg. 14–16).

Taken together, these three reasons suggest that the COVID-19 pandemic does not suffice to show good cause, nor does the combination of the pandemic and the effect of high drug prices. As a result, CMS has not carried its burden of showing good cause to skip notice and comment procedures, and Plaintiff is likely to prevail on its claim that the MFN Rule is procedurally invalid.

C. Public Interest and Balance of Hardships

The Court finds that the balance of the equities and public interest weigh in Plaintiff's favor. Allowing the MFN Rule to go into effect would cause Plaintiff significant financial hardship. (O'Neal Decl. ¶¶ 32–33.) In particular, Plaintiff argues that revenue losses will require it to cut its research and development budget, (O'Neal Decl. ¶¶ 35–36), and that such budget cuts risk restricting medical innovation and limiting Americans' access to new prescription drugs, (Pl.'s Mem. 25). Finally, there is a public interest in providing notice and comment for rules with "far-reaching implications" in order to "foster reasoned decisionmaking." *Nat. Res. Def. Council*, 894 F.3d at 115.

Defendants argue to the contrary, claiming harms from delayed implementation of what they say are congressionally authorized means of reducing the financial burdens of high prescription drug prices. The Court accepts Defendants' premise that "there is inherent harm to an agency in preventing it from enforcing regulations that Congress found it in the public interest to direct that agency to develop and enforce." *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C.

2008), *aff'd sub nom. Cornish v. Doll*, 330 F. App'x 919 (Fed. Cir. 2009). (*See* Defs.' Mem. 27–28.) But, as discussed, the MFN Rule is likely procedurally invalid, so this factor does not weigh in Defendants' favor. Defendants identify an interest in reducing the harms of high drug prices. (*See* Defs.' Mem. 28.) However, as discussed, Defendants delayed more two years from issuing the ANPRM in October 2018 to promulgating the MFN Rule in November 2020, which mitigates this claimed interest. *See* 83 Fed. Reg. 54,546. Thus, any harm from delay lies at Defendants' door. Finally, Defendants identify a public interest in acting quickly to respond to the COVID-19 pandemic. (*Id*.) But, as discussed, there is a mismatch between Defendants' target population and the risks posted by the COVID-19 pandemic, and Amicus's brief reasonably calls into question whether a pandemic is the right time for a large-scale experiment with drug pricing. (Amicus Br. 9–12.)

Taken to its extreme, Defendants' argument dilutes the public interest served by the notice and comment procedures, which are not a mere formality. Instead, they "are designed (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review." *Capital Area Immigrants' Rights Coal. v. Trump*, 471 F. Supp. 3d 25, 44 (D.D.C. 2020) (quoting *Int'l Union, United Mine Workers v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005)); *see also Make the Rd. N.Y. v. Wolf*, 962 F.3d 612, 634 (D.C. Cir. 2020) (noting that "part of the purpose of notice and comment rulemaking is to ensure the parties develop a record for judicial review"). And they "attempt[] to provide a 'surrogate political process' that takes some of the sting out of the inherently undemocratic and unaccountable rulemaking process." *Capital Area Immigrants' Rights Coal.*, 471 F. Supp. 3d at 44

(quoting *Regents of the Univ. of California*, 140 S. Ct. at 1929 n.13, 2020 WL 3271746, at *27 n.13 (Thomas, J., dissenting)). CMS's authority to promulgate the MFN Rule, like any administrative agency's authority to promulgate legislative rules, derives from and is circumscribed by laws enacted by Congress. *See Outdoor Amusement Bus. Ass'n, Inc. v. Dep't of Homeland Sec.*, —— F.3d ——, 2020 WL 7410295, at *8 (4th Cir. Dec. 18, 2020). Thus, any claim by CMS that there is inherent harm in requiring it to comply with the notice and comment requirement ignores the fact that "Congress has . . . determined, in passing the APA, that it is in the public interest to allow the public to comment on proposed regulations prior to their promulgation." *Ass'n of Cmty. Cancer Ctrs.*, 2020 WL 7640818, at *11.

Finally, it bears emphasizing that the Court is not permanently barring CMS from achieving its goal of lowering certain prescription drug prices. Indeed, the relief being sought and granted is a preliminary injunction that merely delays the implementation of the MFN Rule as to one particular prescription medication. "Nor is any burden likely to befall CMS itself as a result of an injunction, as it already has a longstanding reimbursement scheme in place, and it is already committed to accepting comments through much of January." *Id.* Thus, the balance of equities and the public interest favor an injunction.

III. Conclusion

For the reasons given, Plaintiff's application for a preliminary injunction is granted. Pursuant to Federal Rule of Civil Procedure 65(a), Defendants and their agents, servants, employees, attorneys, successors and assigns, and all persons acting in concert with them, are

preliminarily enjoined from applying the MFN Rule to Regeneron's drug EYLEA (aflibercept) Injection, without bond.[6]

SO ORDERED.

DATED: December 30, 2020
White Plains, New York

KENNETH M. KARAS
UNITED STATES DISTRICT JUDGE

[6] No bond is needed because Defendants have not shown a likelihood of financial harm. See *Doctor's Assocs., Inc. v. Distajo*, 107 F.3d 126, 136 (2d Cir. 1997) ("Rule 65(c) gives the district court wide discretion to set the amount of a bond, and even to dispense with the bond requirement 'where there has been no proof of likelihood of harm . . . .'")